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January 11, 2007

VIA E-FILING

The Honorable Gregory M. Sleet
United States District Court
Federal Building
844 North King Street
Wilmington, DE 19801

Re: *Merck & Co., Inc. v. Apotex, Inc.*
C.A. No. 06-230

Dear Judge Sleet:

Apotex's letter of yesterday under Local Rule 7.1.2(c) (D.I. 53) misperceives both the holding of the Supreme Court in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. ____ (2007) and the supposed impact of that decision on the well established rule of *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054 (Fed. Cir. 1995).

The bedrock requirement for declaratory judgment jurisdiction, as affirmed in the *MedImmune* case, is that there must exist a controversy or dispute that is "definite and concrete, touching the legal relations of parties having adverse legal interests." *See MedImmune* at 7-8. In this case, there is no such controversy because Merck's covenant not to sue has removed any adversary character from the legal relationship between Merck and Apotex concerning the patents in suit. It is as if the patents do not exist insofar as any definite and concrete plans Apotex may have in mind.

Apotex complains that it is "prevented" from a market opportunity. However, that prevention is not as a result of Merck's lawsuit, but rather because of the regulatory scheme of the Hatch-Waxman Act. Moreover, in *Apotex, Inc. v. FDA*, 449 F.3d 1249, 1253 (D.C. Cir. 2006), the court recognized this situation under which the FDA attributes different significance to dismissals for lack of jurisdiction and dismissals for invalidity, unenforceability or noninfringement, holding that such a distinction is "in no way inconsistent with the language of the [Hatch-Waxman Act]."

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The fact that Apotex might benefit in some ancillary way from different types of dismissals does not create a controversy about Merck's patents in which Merck is required to participate. If that were so, interested companies could post bounties for any person to succeed in having specific patents held invalid, and the challengers, without any other interest other than that reward, could cite it as the basis for declaratory judgment jurisdiction.

Both *MedImmune* and *Super Sack* make it clear that declaratory judgment jurisdiction requires a concrete dispute the subject matter of which affects the legal relationship between the parties. The Merck patents afford no basis for such jurisdiction, and Merck's motion to dismiss should be granted.

Respectfully,

/s/ Mary B. Graham

Mary B. Graham (#2256)

MBG/dam

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